4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2001-D-0067]

Providing Submissions in Electronic Format--Postmarketing Safety Reports; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Providing Submissions in Electronic Format--Postmarketing Safety Reports." This guidance provides general information pertaining to electronic submission of postmarketing safety reports (individual case safety reports (ICSRs), attachments to ICSRs (ICSR attachments), and other postmarketing safety reports) for certain human drugs, biological products, and combination products. This guidance finalizes the revised draft guidance entitled "Providing Submissions in Electronic Format--Postmarketing Safety Reports," issued in June 2014.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment

does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2001-D-0067 for "Providing Submissions in Electronic Format--Postmarketing Safety Reports." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *For information concerning human drug product*s: Suranjan De, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4307, Silver Spring, MD 20993-0002, 240-402-0498.

*For information concerning human biological product*s: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Providing Submissions in Electronic Format--Postmarketing Safety Reports." This guidance provides general information pertaining to electronic submission of postmarketing safety reports (ICSRs, ICSR attachments, and other postmarketing safety reports) under the following provisions:

- 21 CFR 314.80 and 314.98 (regarding products with approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs), respectively, including combination products or drug constituent parts with approved NDAs or ANDAs)
- 21 CFR 600.80 (regarding products with approved biologics license applications (BLAs), including combination products or biological product constituent parts with approved BLAs)
- 21 CFR part 4, subpart B (requiring additional reports for combination products with approved NDAs, ANDAs, or BLAs)
- 21 CFR 310.305 (regarding prescription drug products marketed for human use without approved NDAs or ANDAs, including prescription drug products that are compounded by facilities registered as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b))

- 21 CFR 329.100 and section 760 of the FD&C Act (21 U.S.C. 379aa) (regarding nonprescription drug products marketed for human use without approved NDAs or ANDAs)

This guidance does not apply to the following: vaccines, human cells, tissues, and cellular tissue-based products regulated under section 361 of the Public Health Service Act (42 U.S.C. 264), whole blood or blood components, combination products with a drug or biological product constituent part marketed under a device application, or lot distribution reports.

On June 10, 2014, FDA published a final rule (79 FR 33072) to amend its postmarketing safety reporting regulations for human drug and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that the Agency can process, review, and archive. Elsewhere in the June 10, 2014, *Federal Register* (79 FR 33220), FDA announced the availability of a revised draft guidance entitled "Providing Submissions in Electronic Format--Postmarketing Safety Reports," which revised and replaced the draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Postmarketing Individual Case Safety Reports," issued on June 12, 2008 (73 FR 33436). The guidance announced in this current notice finalizes the June 10, 2014, revised draft guidance of the same title. The Agency considered comments on the draft guidance while finalizing the guidance. Generally, we revised the draft guidance to update and clarify topics, such as: (1) options for transmitting reports in electronic format; (2) the notification that submitters will receive when FDA has received the electronic postmarketing safety report; (3) requesting temporary waivers from the electronic submission requirement; and (4) information on the receipt date of electronic submissions in the case of submission failure.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Providing Submissions in Electronic Format--Postmarketing Safety Reports." It does not establish any

rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 pertaining to postmarketing reporting of adverse drug experiences, including periodic and followup reports, have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 207 pertaining to registration of producers of drugs and listing of drugs in commercial distribution have been approved under OMB control number 0910-0045. The collections of information in 21 CFR parts 310, 314, and 600 pertaining to postmarketing reporting of adverse drug experiences for drugs subject to an NDA have been approved under OMB control number 0910-0291 (MedWatch Forms FDA 3500, 3500A, and 3500B). The collections of information in 21 CFR parts 310 and 314 pertaining to: (1) postmarketing reporting of adverse drug experiences for drugs without approved NDAs and the collections of information and (2) the submissions required by section 760 of the FD&C Act for nonprescription human drug products marketed without an approved application have been approved under OMB control number 0910-0230. The collections of information in 21 CFR part 600 for biological drug products have been approved under OMB control number 0910-0308. The collections of information pertaining to the electronic submission of adverse event reports in 21 CFR parts 310, 314, and 329 have been approved under OMB control number 0910-0645. The collections of information pertaining to submissions required for outsourcing facilities under section 503B of the FD&C Act have been approved under OMB control number 0910-0800. The collections of information in 21 CFR part 4 pertaining to postmarketing safety information

sharing by constituent part applicants for combination products have been approved under OMB control number 0910-0834.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Dated: April 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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